IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Galveston Division

TEXAS DEPARTMENT OF CRIMINAL JUSTICE, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, SCOTT GOTTLIEB, in his official capacity as the Commissioner of Food and Drugs, and UNITED STATES OF AMERICA, Defendants.	)	Civil Action No. 3:17-cv-00001

PLAINTIFF TEXAS DEPARTMENT OF CRIMINAL JUSTICE'S SECOND AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. In this case, Plaintiff Texas Department of Criminal Justice ("TDCJ") challenges actions by the U.S. Food and Drug Administration ("FDA") prohibiting importation of a shipment of the drug thiopental sodium. TDCJ is responsible for administering criminal sentences in Texas and has attempted to import the drug to carry out capital sentences through lethal injection. The statutory and regulatory requirements that FDA invokes to support its prohibitory actions do not apply in this law enforcement context. An FDA "law enforcement" exemption precludes application of one of the requirements at issue. And the remaining requirements also do not apply, among other things because the drugs have labeling that does not prescribe, recommend, or suggest any patient treatment use. TDCJ therefore respectfully requests the Court to set aside FDA's prohibitory actions, declare that they are unlawful, and enjoin FDA from imposing similar prohibitions in the future.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action under 28 U.S.C. § 1331, to provide remedies set forth in 5 U.S.C. § 706 and 28 U.S.C. § 2201.

3. Venue is proper in this District under 28 U.S.C. § 1391(e)(1)(B), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred, and the property that is the subject of this action is situated, in this District. Venue also is proper in this District under 28 U.S.C. § 1391(e)(1)(C), because Plaintiff resides in this District.

PARTIES

4. Plaintiff TDCJ is a law enforcement agency of the State of Texas with headquarters in this District, at 861-B IH 45 North, Huntsville, Texas. TDCJ administers correctional facilities within this District and throughout the State of Texas. TDCJ is the sole agency in the State of Texas with the authority and responsibility to administer lawfully-imposed capital sentences through lethal injection. For purposes of this suit, TDCJ represents the interests of the State of Texas.

5. Defendant FDA has federal regulatory authority over, and has refused admission into domestic commerce of, the thiopental sodium drugs at issue in this case. Defendant Scott Gottlieb is the Commissioner of Food and Drugs and the top official of Defendant FDA. Defendant Gottlieb is named as a defendant in his official capacity as the Commissioner of Food and Drugs. Defendant United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of actions of agencies of the United States that have affected Plaintiff adversely and will continue to do so unless remedied by this Court.

STATUTORY AND REGULATORY BACKGROUND

FDA's Approval Process for "New Drugs"

6. The Federal Food, Drug, and Cosmetic Act ("FFDCA") establishes a premarket approval process that requires FDA approval before pharmaceuticals known as "new drugs" may be distributed in interstate commerce. 21 U.S.C. § 355(a). In order to obtain FDA approval to market and sell a brand-name "new drug," the sponsoring company must submit a New Drug Application ("NDA"). An NDA must outline and

explain the drug's ingredients, the results of clinical tests, the results of animal studies, how the drug behaves in the body, and how the drug is manufactured, processed, and packaged. Before approving an NDA, FDA must evaluate numerous statutorily-defined criteria, including whether the drug is safe and effective for its intended use. *See* 21 U.S.C. §§ 355(b), (d).

7. In order to obtain FDA approval to market and sell a generic "new drug," the sponsoring company typically must submit an Abbreviated New Drug Application ("ANDA"). An ANDA applicant may obtain FDA approval without conducting the full battery of clinical and non-clinical studies required for an NDA. *See generally* 21 U.S.C. § 355(j). An ANDA applicant may rely upon a prior FDA finding of safety and efficacy for the approved brand-name drug that is referred to in the ANDA, provided that the proposed generic drug is the "same" with regard to active ingredients, dosage form, route of administration, strength, and labeling. *Id*. § 355(j)(2)(A)(i), (ii), (iii), and (v).

8. FDA premarket approval requirements apply only to "new drugs" as that term is defined in 21 U.S.C. § 321(p). For FDA to demonstrate that a drug is a "new drug," the agency must establish that it is (1) not generally recognized by pertinent experts as "safe and effective for use under the conditions prescribed, recommended, or suggested in" the drug's labeling; or (2) a drug that has become so recognized as a result of certain investigations, but which has not, other than in those investigations, been used to a material extent or for a material time under such conditions. 21 U.S.C. § 321(p). The FFDCA defines "labeling" as "all labels and other written, printed, or graphic matter

(1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

9. Determining a drug's "new drug" status based on statements in its labeling is a fundamental foundation of FDA's drug approval regime. A drug may be "generally recognized as safe and effective" for some uses but not for others. *See, e.g.*, 21 C.F.R. § 330.1(c)(2). Labeling statements identify the uses for which approval is required (absent general recognition of safety and effectiveness for that use). The approval standard accordingly parallels the "new drug" standard. FDA bases approval of a brand-name new drug (through an NDA) on adequate and well-controlled investigations of the drug's effectiveness "under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). When it approves an NDA, FDA determines that the brand-name new drug is safe and effective "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *See* 21 U.S.C. §§ 355(d)(1), (d)(5).

10. The approval of a generic version of a brand-name "new drug" is similarly tied fundamentally to conditions of use prescribed, recommended, or suggested in the labeling. An ANDA must contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved" for the corresponding brand-name drug. 21 U.S.C. § 355(j)(2)(A)(i); *see also* 21 C.F.R. § 314.94(a)(4)(i). For FDA to approve the ANDA, the agency must determine that (absent certain exceptions) "the labeling proposed for the

drug is the same as the labeling approved for" the corresponding brand-name drug. 21 U.S.C. § 355(j)(4)(G).

Drugs That May be Lawfully Marketed Without FDA Premarket Approval

11. If a drug is generally recognized by pertinent experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling, the drug is not a "new drug" within the meaning of 21 U.S.C. § 321(p). Accordingly, such a drug may be lawfully marketed without prior FDA approval. FDA promulgates monograph regulations defining the conditions under which many such drugs are generally recognized as safe and effective. Numerous drugs are currently marketed lawfully without prior FDA approval, because the drugs comply with these monograph requirements. *See generally* 21 C.F.R. pts. 330-361.

12. The FFDCA also does not require premarket approval of a drug if it has *no* conditions of use prescribed, recommended, or suggested in a drug's labeling. It is not possible for FDA to establish that such a drug is a "new drug," because there are no conditions of use prescribed, recommended, or suggested in the labeling for the agency to evaluate for general recognition of safety and effectiveness. Because such a drug is not a "new drug," premarket approval requirements do not apply. If FDA wishes to restrict distribution of an unapproved drug with no conditions of use prescribed, recommended, or suggested in its labeling, the agency does so through other regulatory requirements.

The "Adequate Directions for Use"
Requirement and the Law Enforcement Exemption

13. 21 U.S.C. § 352(f)(1) is one of the provisions that FDA typically relies upon if it wishes to restrict distribution of an unapproved drug with no conditions of use prescribed, recommended, or suggested in its labeling. Section 352(f)(1) states that a drug "shall be deemed to be misbranded . . . unless its labeling bears adequate directions for use." FDA's regulations provide that "[a]dequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. A drug that has no conditions of use prescribed, recommended, or suggested in its labeling generally lacks adequate directions for use, because its labeling omits "[s]tatements of all conditions, purposes, or uses for which such drug is intended." *Id*. § 201.5(a).

14. A drug that is misbranded under section 352(f)(1) because it lacks adequate directions for use in its labeling is subject to a range of enforcement remedies under the FFDCA, including import refusal, seizure, and injunction. 21 U.S.C. §§ 331(a), 332(a), 334(a), 381(a).

15. Section 352(f)(1) authorizes FDA to promulgate regulations exempting drugs from the "adequate directions for use" requirement if that requirement "is not necessary for the protection of the public health." Under this authority FDA has exempted numerous categories of drugs from the "adequate directions for use" requirement.

16. This case involves one such drug labeling exemption: 21 C.F.R. § 201.125, which governs "[d]rugs for use in teaching, law enforcement, research, and analysis." Section 201.125 applies to prescription drugs as defined in 21 U.S.C. § 353(b)(1)(A). Under section 201.125, a prescription drug is "exempt from [21 U.S.C. § 352(f)(1)] if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing." 21 C.F.R. § 201.125.

17. In this case, the drugs at issue fall within the exemption that applies to drugs "shipped or sold to . . . persons . . . engaged in law enforcement, . . . and [are] to be used only for such . . . law enforcement." 21 C.F.R. § 201.125.

Requirements for Warnings to Protect Patients

18. The FFDCA also requires that patients who use drugs are protected by necessary and adequate labeling warnings. 21 U.S.C. § 352(f)(2) states that a drug "shall be deemed to be misbranded . . . unless its labeling bears . . . such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users."

19. In this case, no labeling warnings are necessary to protect patients, among other things because the drugs at issue will not be used for patient treatment.

FDA's Process for Refusing Admission of Imports Into Domestic Commerce

20. The FFDCA establishes a regime in which FDA and the U.S. Bureau of Customs and Border Protection ("Customs") work together to admit into domestic commerce (or refuse admission of) drugs that are offered for import. In general, Customs has the formal responsibility to police the border (just as it does for all other products offered for import), and FDA provides the substantive expertise necessary to evaluate whether drugs should be admitted into domestic commerce.

21. The FFDCA gives Customs authority to collect samples of drugs offered for import and deliver them to FDA, at FDA's request. 21 U.S.C. § 381(a). In practice, Customs has delegated this authority to FDA, so that FDA is the agency that collects the samples. When FDA decides to collect a sample, FDA detains the drugs by issuing a "hold" order that prevents introduction of the drugs into domestic commerce. The drugs are detained for purposes of the examination described below. 21 C.F.R. § 1.90.

22. The FFDCA gives FDA authority to conduct an "examination" of a sample of imported drugs. 21 U.S.C. § 381(a). The purpose of the examination is for FDA to determine whether the agency should refuse the drugs' admission into domestic commerce. *Id.* Section 381(a) allows FDA to refuse admission of a drug into domestic commerce, among other things, if the drug violates the premarket approval requirements of 21 U.S.C. § 355 or the misbranding requirements of 21 U.S.C. § 352.

23. If FDA determines that any of the enumerated statutory criteria for refusal of admission have been met (21 U.S.C. § 381(a)), FDA issues a "Notice of FDA Action" order that detains the drugs and prevents their admission into domestic commerce. At the

same time, FDA gives the owner or consignee notice and an opportunity for an informal hearing. 21 U.S.C. § 381(a); 21 C.F.R. § 1.94(a). If the owner or consignee persuades the agency that the drugs should not be refused, FDA issues a "Notice of FDA Action" order also known as a "Notice of Release," which admits the drugs into domestic commerce. If FDA decides to refuse admission of the drugs, the agency issues a "Notice of FDA Action" order also known as a "Notice of Refusal." "Notices of Release" and "Notices of Refusal" are "orders" within the meaning of 5 U.S.C. § 551(6) because they are the final disposition of FDA in a matter other than rulemaking.

24. An FDA Notice of Refusal is final and definitive, not tentative or interlocutory. A Notice of Refusal definitively effectuates FDA's final determination that it is unlawful to distribute the refused drugs in interstate commerce. A Notice of Refusal and the underlying substantive determination that an import is refused, is a final agency action within the meaning of 5 U.S.C. § 704, because it marks the consummation of the agency's decision-making process regarding admissibility of the drugs into domestic commerce and determines rights or obligations, or triggers legal consequences, concerning the drugs offered for import.

25. Customs enforces FDA's final agency action refusing admission of an import. For most imported drugs, Customs conditionally releases the drugs to the custody of their owner or consignee at the time of importation, provided that the importer posts a bond that would be forfeited if the drugs are not returned to Customs custody when requested. 19 C.F.R. § 113.62. If FDA issues a Notice of Refusal for such drugs, Customs (under the basic importation bond) enforces FDA's final agency action by

demanding redelivery of the drugs from the owner or consignee, so that Customs can require their export or destruction (with the owner or consignee choosing whether the drugs will be exported or destroyed). 19 C.F.R. § 141.113(c)(3); 21 U.S.C. § 381(a).

26. Under very unusual circumstances, even where the owner or consignee has otherwise complied with the basic importation bond requirements, Customs does not release the drugs to the custody of their owner or consignee at the time of importation and instead transfers the drugs to the custody of FDA pending consideration of their admissibility into domestic commerce. If FDA later issues a Notice of Refusal for such drugs, Customs enforces FDA's final agency action by requiring their export or destruction (with the owner or consignee choosing whether the drugs will be exported or destroyed). 21 U.S.C. § 381(a).

PREDICT

27. FDA has implemented an electronic screening tool for import operations called Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting ("PREDICT"). PREDICT uses automated data mining and pattern discovery processes to create a different customized risk score for every import line within every import entry involving a product regulated by FDA. PREDICT assigns a risk score to every import line based on an electronic assessment of information in an FDA database, including information regarding the compliance history of the foreign manufacturer and importer and the characteristics of the specific product being imported. The risk score cumulates different risks identified in the database. Imported products determined by PREDICT to be of sufficiently lower risk are given an automated "May Proceed," which automatically

authorizes the products to enter domestic commerce without any review by FDA personnel (provided that they are not held due to any other screening criteria). Imported products determined by PREDICT to be higher risk are flagged for review by FDA personnel for possible further review, including detention.

28. When FDA refuses an import entry of drugs, the refusal is entered into the PREDICT database and added to the compliance history for the drug and its importer. Through the operation of the PREDICT system, FDA's refusal of one import materially increases the risk scores for the drug and its importer. By materially increasing the risk scores, FDA's refusal of a single import materially reduces the chance that future imports of the same drug by the same importer will automatically be admitted into domestic commerce, without review by FDA personnel. By materially increasing the risk scores, FDA's refusal of a single import materially increases the chance that future imports of the same drug by the same importer will be detained at the border and scrutinized for possible compliance issues by FDA personnel.

THE PARTIES' DISPUTE

29. This case arises out of a dispute concerning the importation of a drug (thiopental sodium) by TDCJ solely for a law enforcement use: effectuating lawfully-imposed capital sentences through lethal injection.

30. Thiopental sodium is a barbiturate that produces unconsciousness and anesthesia. This effect is well known; the drug has been used for purposes of anesthesia since before the FFDCA was enacted in 1938. Thiopental sodium has been used in hospitals for many decades as a prescription anesthetic. In addition, for many years and

in numerous different jurisdictions, thiopental sodium has been used (alone or in combination with other drugs) to impose capital sentences through lethal injection.

31. TDCJ has previously purchased and used thiopental sodium in numerous executions before it became commercially unavailable to Texas correctional facilities for that purpose. Through the import at issue in this case, TDCJ is attempting once again to utilize thiopental sodium for purposes of imposing lawful capital sentences.

FDA's Rules Governing Imports of
Thiopental Sodium to be Used by Correctional Facilities

32. On January 5, 2011, FDA adopted a document entitled "Guidance for handling pending and future shipments of Sodium Thiopental." Sodium thiopental and thiopental sodium are different names for the same drug. The January 2011 "Guidance" was a "rule" within the meaning of 5 U.S.C. § 551(4) because it was an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.

33. The January 2011 rule established the FDA procedures governing admissibility of all imports of sodium thiopental intended to be shipped to correctional facilities. The January 2011 rule directed all applicable FDA personnel to release such imports automatically into domestic commerce for shipment to correctional facilities and exempted such imports from the normal process through which the agency would determine admissibility of an import.

34. On March 28, 2012, FDA revoked the January 2011 rule. On April 16, 2012, FDA issued a new "DIOP Procedure" (entitled "Processing of Sodium Thiopental

Entries") governing admissibility of all imports of sodium thiopental intended to be shipped to correctional facilities. DIOP was FDA's Division of Import Operations and Procedure (for which the pertinent agency unit has more recently been renamed the Division of Import Operations ("DIO")). The 2012 DIOP Procedure (and related written or unwritten implementation procedures) constitute a "rule" within the meaning of 5 U.S.C. § 551(4) as an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. On information and belief, the 2012 DIOP Procedure is still in effect (having been amended only once, in September 2012, to change the numbering in the document but not the substance) and is binding on the agency.

35. Among other things, the 2012 DIOP Procedure:

a. States that "[i]n the past, FDA has released shipments of sodium thiopental being imported by or on behalf of state correctional authorities. FDA did not review or approve products for the purpose of lethal injection and has not reviewed the products to determine their identity, safety, effectiveness, purity or any other characteristics. On March 27, 2012, the United States District Court for the District of Columbia has ordered FDA not to allow the entry of sodium thiopental into interstate commerce. Therefore, entries of sodium thiopental to correctional facilities shall be processed according to these procedures.";

b. Directs FDA District Offices to "ensure[ ]" that import entries of sodium thiopental are handled in accordance with the 2012 DIOP Procedure, including by (1) entering, in import entry documentation, the statement "[d]o not release this line or request detention of this line without direct instructions to do so from District or Headquarters management"; (2) contacting the Customs office covering the pertinent port of entry and requesting that they "do not allow the shipment to leave the port"; and (3) emailing DIOP (now DIO) "the request to [Customs] to hold the shipment, and the [Customs] response (or indicate [Customs] did not respond)";

c. Directs FDA's DIOP (currently DIO) Operations Branch to review a daily report of sodium thiopental import entries provided by DIOP Systems Branch and notify the FDA Commissioner's Office and other offices within FDA about all such import entries; and

d. Directs FDA's DIOP (currently DIO) Systems Branch to maintain a daily report of shipments of sodium thiopental offered for import and to ensure appropriate screening of entries to appropriately flag entries of sodium thiopental.

The Drugs Offered for Import

36. Each vial of drug offered for import by TDCJ and at issue in in this case bears a label identifying the drug as thiopental sodium and containing the legend: "For law enforcement purpose only." There are no statements in the drug's label or labeling

prescribing, recommending, suggesting, or otherwise addressing the drug's conditions of use. The thiopental sodium is listed with FDA, and was manufactured and labeled at a foreign facility registered with FDA, consistent with applicable regulatory requirements. *See* 21 C.F.R. § 207.40.

37. The label for each vial of thiopental sodium also includes an "Rx Only" legend and a "CIII" legend (indicating that the drug is a schedule III controlled substance). Consistent with applicable regulations, TDCJ is registered with the Drug Enforcement Administration ("DEA") as an importer of this drug. *See* 21 U.S.C. § 957(a)(1).

The Procedures Followed by TDCJ Prior to Importation

38. On May 29, 2015, in response to a press inquiry, FDA's Acting Deputy Director, Strategy in the agency's Office of Media Affairs stated in an email that "Sodium thiopental is unlawful to import for purposes of lethal injection, and that applies to all states who intend to use it for that purpose."

39. On June 8, 2015, TDCJ filed a Controlled Substance Import Declaration with DEA explaining that TDCJ proposed to import thiopental sodium intended for law enforcement purposes.

40. After a number of communications between DEA and TDCJ, DEA issued a written response on July 13, 2015, stating that DEA would notify Customs and FDA of the upcoming importation. According to DEA, FDA had contacted DEA and asserted that it was illegal to import the drug.

41. On July 24, 2015, a foreign distributor shipped 1000 vials of thiopental sodium via air freight to TDCJ. The shipment arrived at the Houston, Texas international airport the same day. TDCJ paid the distributor for the drugs at approximately the same point.

FDA's Detention of the Thiopental Sodium

42. FDA examined the goods by July 29, 2015. Following an initial detention of the goods by FDA that was rescinded without explanation, Customs detained the goods on August 5, 2015. The Customs Detention Notice indicated that the goods were detained at the request of FDA " . . . for FDA [admissibility] and further analysis."

43. On August 24, 2015, FDA issued a new notice of detention. The notice of detention alleged that the detained shipment of thiopental sodium appears to: "(1) lack adequate directions for use" in violation of 21 U.S.C. § 352(f)(1); "(2) lack adequate warning against use in pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to protect users" in violation of 21 U.S.C. § 352(f)(2); and "(3) be a new drug without an approved new drug application" in violation of 21 U.S.C. § 355(a).

The Informal Hearing on Admissibility

44. On October 23, 2015, TDCJ filed a written submission with FDA presenting written testimony, argument and exhibits in connection with the informal hearing on refusal of admission required by 21 C.F.R. § 1.94.

45. TDCJ's October 23 submission explained that the drugs do not violate the "adequate directions for use" requirement of 21 U.S.C. § 352(f)(1), because the drugs fall

within the "law enforcement" exemption to that requirement established by FDA regulation (21 C.F.R. § 201.125).

46. TDCJ's October 23 submission also explained that the drugs do not violate the warning requirement of 21 U.S.C. § 352(f)(2), because that requirement does not apply under circumstances where there are no patients using the drugs. In the alternative, TDCJ argued that even if the requirement did apply, the "law enforcement purpose only" legend on the drugs' label satisfied the requirement.

47. Finally, TDCJ's October 23 submission explained that the drugs at issue do not violate the drug approval requirements of 21 U.S.C. § 355(a), because those requirements only apply to "new drugs," and the thiopental sodium at issue is not a "new drug," because there are no conditions of use prescribed, recommended, or suggested in its labeling.

48. On April 15, 2016, FDA issued a Tentative Decision on admissibility of the drugs. The Tentative Decision stated that the agency had tentatively determined that the thiopental sodium appeared to be an unapproved new drug that violated 21 U.S.C. § 355(a) and appeared to be a misbranded drug that violated 21 U.S.C. §§ 352(f)(1) and 352(f)(2).

49. TDCJ submitted its response to FDA's Tentative Decision on May 20, 2016, explaining again that the thiopental sodium did not violate any of the three statutory provisions at issue.

FDA's Order Refusing Admission of the Thiopental Sodium

50. On April 21, 2017, FDA issued a Notice of Refusal refusing admission of the thiopental sodium into domestic commerce on the ground that the drugs appeared to lack adequate directions for use (in violation of 21 U.S.C. § 352(f)(1)) and appeared to be unapproved new drugs (in violation of 21 U.S.C. § 355(a)). The Notice of Refusal states that the drugs must be re-exported or destroyed within 90 days, or within such additional time as the District Director of Customs specifies. Currently the refused thiopental sodium remains detained in the custody of FDA in this District.

51. FDA explained the substantive basis for the refusal in an April 20, 2017 memorandum. In the memorandum, FDA presented legal arguments supporting its determination that the drugs appeared to lack adequate directions for use (in violation of 21 U.S.C. § 352(f)(1)) and appeared to be unapproved new drugs (in violation of 21 U.S.C. § 355(a)). Although FDA's detention notice and April 15, 2016 Tentative Decision had included an additional claim (alleging a violation of 21 U.S.C. § 352(f)(2)), the April 20, 2017 memorandum dropped that claim (as did the April 21, 2017 Notice of Refusal).

52. The Notice of Refusal was issued by an FDA Compliance Officer, and the related memorandum was signed by the Acting Director of FDA's Southwest Import District Office. These officials had the authority to, and did, make the agency's final decision on admissibility of the drugs, as the officers designated by the FDA District Director to act on the District Director's behalf in administering and enforcing the agency's refusal authority. *See* 21 C.F.R. §§ 1.83(b), 1.94.

53. The Notice of Refusal (and related memorandum) is an "order" within the meaning of 5 U.S.C. § 551(6) because it is a final disposition in a matter other than rulemaking. We refer to the Notice of Refusal and related memorandum hereafter as the "refusal order."

54. The refusal order is a final and definitive, not tentative or interlocutory, determination that it is unlawful to distribute the refused thiopental sodium in domestic commerce. The refusal order is a final agency action within the meaning of 5 U.S.C. § 704, because it marked the consummation of the agency's decision-making process regarding admission of the drugs into domestic commerce and determined rights or obligations, or triggered legal consequences, concerning the drugs.

55. The refusal order directly harms TDCJ by preventing TDCJ from having the option of using the drugs at issue in lawful executions. This harm will continue unless and until the Court issues the remedies requested below.

56. The refusal order also independently and directly harms TDCJ economically by preventing it from receiving products for which TDCJ already has paid. This harm will continue unless and until the Court issues the remedies requested below.

57. The refusal order also independently and directly harms TDCJ by injuring TDCJ's reputation. In the refusal order, FDA has formally decided that TDCJ — a law enforcement agency — has attempted to import drugs in violation of federal law. The refusal order has caused, and is substantially likely to continue to cause, adverse publicity that has and will injure TDCJ's reputation by asserting that TDCJ has attempted to import

drugs in violation of federal law. These injurious collateral consequences of the refusal order will continue until the Court issues the remedies requested below.

58. The refusal order also injures TDCJ by directly causing a substantial risk of continuing and future harm to TDCJ. There currently are more than 200 offenders who have received a capital sentence in Texas and are awaiting execution through lethal injection. During recent years, TDCJ has executed numerous prisoners by administering lethal injection. TDCJ will continue to execute additional prisoners through lethal injection, on a recurring and continuing basis, for the foreseeable future. TDCJ therefore needs a continuing and recurring supply of drugs to be used for lethal injection. TDCJ intends to continue importing thiopental sodium, with the same labeling as the import currently under dispute, for purposes of lethal injection. The refusal order creates a substantial risk that FDA will detain and refuse, or direct Customs to detain so that FDA will refuse, future shipments of thiopental sodium that TDCJ wishes to import into the United States. The substantial risk of detention and substantial risk of refusal are separate and independent harms, each of which independently justifies this Court's intervention. This substantial risk of these harms will continue unless and until the Court issues the remedies requested below.

59. The refusal order creates a substantial risk that FDA will harm TDCJ by detaining (or directing Customs to detain) future shipments of thiopental sodium that TDCJ wishes to import into the United States, because the 2012 DIOP Procedure described above (among other things) directs FDA personnel (1) to monitor and screen for thiopental sodium import entries on a daily basis; (2) not to release such shipments

without further instructions; and (3) to request Customs to hold such shipments pending further instructions from FDA, and because the further instructions will be that the shipments must be detained and refused, based on the rationales and conclusions in the refusal order. The probability of such detentions is further magnified because, on information and belief, information regarding the refusal order either has been or will be entered into the PREDICT database, and entry of the refusal order into the PREDICT database independently and materially increases the chance that FDA will detain such future imports.

60. The refusal order also creates a substantial risk that FDA will harm TDCJ by detaining (or directing Customs to detain) future shipments of thiopental sodium that TDCJ wishes to import into the United States, because FDA and DEA jointly scrutinize such shipments prior to their importation, and the refusal order has determined that such shipments are unlawful. FDA and DEA are in communication regarding the regulatory status of thiopental sodium. DEA regulations require TDCJ to file a new Controlled Substance Import Declaration with DEA before initiating each such future import. The Controlled Substance Import Declaration notifies DEA in advance that a controlled substance is to be imported into the United States. When TDCJ files Controlled Substance Import Declarations in connection with future imports of thiopental sodium, it is highly likely that DEA will notify FDA of the proposed imports, and that (based on the refusal order) FDA either will detain the drugs or direct Customs to detain the drugs.

61. There is a substantial risk that because of the refusal order, FDA will further harm TDCJ by refusing such future imports when they are detained, because FDA

will follow the rationale of the refusal order in denying the admission of such imports into domestic commerce. Before the import shipment of the drugs at issue was even commenced by the foreign distributor, FDA (1) concluded, in the 2012 DIOP Procedure, that FDA was not permitted to allow the entry of sodium thiopental into interstate commerce; (2) announced categorically, in the press, that it is unlawful for any state to import sodium thiopental for purposes of lethal injection; and (3) informed DEA that the forthcoming shipment was unlawful. In addition, for a period of almost two years, FDA analyzed the lawfulness of TDCJ's import and has issued its final determination on that issue. There is no realistic possibility that FDA would reach a different determination regarding the admissibility of future imports by TDCJ of the same drug, with the same labeling, to be used for the same purpose. Such refusals will directly harm TDCJ by preventing TDCJ from having the option of using the drugs at issue in lawful executions. The remedies requested below will redress this harm.

62. In the alternative, based on the facts set forth in the foregoing paragraphs, TDCJ at a minimum has a reasonable expectation that when it imports future shipments of thiopental sodium with the same labeling, FDA will refuse the import, based on the same legal analysis set forth in the refusal order challenged in this case, unless a court intervenes.

63. There is no adequate judicial remedy that is an alternative to the remedies requested in this Complaint.

COUNT I
Agency Action in Excess of Statutory Jurisdiction, Authority, or Limitations
(21 U.S.C. §§ 355(a) and 381(a) – Refusal Order)

64. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 63 above.

65. The refused thiopental sodium does not violate, or appear to violate, any provision of the FFDCA. Admission of the refused thiopental sodium into domestic commerce is lawful.

66. In the refusal order, FDA erroneously concluded that the refused thiopental sodium is or appears to be an unapproved new drug that violates, or appears to violate, 21 U.S.C. § 355(a).

67. The refused thiopental sodium may be lawfully admitted into domestic commerce without prior FDA approval. The approval requirements of 21 U.S.C. § 355(a) do not apply to drugs with labeling that does not prescribe, recommend, or suggest any conditions of use for the drugs, because such drugs are not "new drugs" within the meaning of 21 U.S.C. § 321(p). The labeling of the refused thiopental sodium does not prescribe, recommend, or suggest any conditions of use for that drug. Therefore the approval requirements of 21 U.S.C. § 355(a) do not apply to the refused thiopental sodium.

68. The refusal order is a final agency action that prohibited importation of thiopental sodium without statutory authority. FDA had no authority to refuse admission of the drugs under 21 U.S.C. § 381(a), because the drugs do not violate, and do not appear to violate, 21 U.S.C. § 355(a). The refusal order is a final agency action in excess

of statutory jurisdiction, authority, or limitations within the meaning of 5 U.S.C. § 706(2)(C).

69. Under 5 U.S.C. § 706(2)(C), this Court should hold unlawful and set aside the refusal order and order FDA to release the drugs to TDCJ.

70. Under 5 U.S.C. § 706(2)(C) and 28 U.S.C § 2201, this Court should declare the refusal order unlawful and direct FDA to provide notice of that declaratory judgment to Customs and DEA.

71. Under 5 U.S.C. § 706(2)(C), this Court should enjoin FDA from refusing admission into domestic commerce of future imports of thiopental sodium with the same labeling. The injunction also should direct FDA to remove references to the refusal order from the PREDICT database.

COUNT II
Agency Action in Excess of Statutory Jurisdiction, Authority, or Limitations
(21 U.S.C. §§ 352(f)(1) and 381(a) – Refusal Order)

72. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 63 above.

73. The refused thiopental sodium does not violate, or appear to violate, any provision of the FFDCA. Admission of the refused thiopental sodium into domestic commerce is lawful.

74. In the refusal order, FDA erroneously concluded that the refused thiopental sodium is misbranded, or appears to be misbranded, within the meaning of 21 U.S.C. § 352(f)(1). The drugs are exempt from the requirements of section 352(f)(1) under 21 C.F.R. § 201.125.

75. The refused thiopental sodium is a prescription drug within the meaning of 21 U.S.C. § 353(b)(1)(A).

76. Use of thiopental sodium to administer lawfully-imposed capital sentences through lethal injection is a use of the drug for law enforcement purposes. TDCJ is a state agency that is regularly and lawfully engaged in law enforcement. The refused thiopental sodium is exempt from the requirements of 21 U.S.C. § 352(f)(1) under 21 C.F.R. § 201.125, because the drugs were shipped or sold to persons engaged in law enforcement, and the drugs are to be used only for such law enforcement.

77. The refusal order is a final agency action that prohibited importation of thiopental sodium without statutory authority. FDA had no authority to refuse admission of the drugs under 21 U.S.C. § 381(a), because the drugs are not misbranded, and do not appear to be misbranded, under 21 U.S.C. § 352(f)(1). The refusal order is a final agency action in excess of statutory jurisdiction, authority, or limitations within the meaning of 5 U.S.C. § 706(2)(C).

78. Under 5 U.S.C. § 706(2)(C), this Court should hold unlawful and set aside the refusal order and order FDA to release the drugs to TDCJ.

79. Under 5 U.S.C. § 706(2)(C) and 28 U.S.C § 2201, this Court should declare the refusal order unlawful and direct FDA to provide notice of that declaratory judgment to Customs and DEA.

80. Under 5 U.S.C. § 706(2)(C), this Court should enjoin FDA from refusing admission into domestic commerce of future imports of thiopental sodium with the same

labeling. The injunction also should direct FDA to remove references to the refusal order from the PREDICT database.

PRAYER FOR RELIEF

Plaintiff respectfully requests the Court to grant the following relief:

I. Hold unlawful and set aside FDA's refusal order and order FDA to release the drugs to TDCJ;

II. Issue the declaratory judgment described in paragraphs 70 and 79 above and direct FDA to inform Customs and DEA of that declaratory judgment;

III. Issue the injunction described in paragraphs 71 and 80 above; and

IV. Award such other relief as this Court deems just and proper.

Respectfully submitted,

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May 22, 2017

Attorneys for Plaintiff Texas Department of Criminal Justice

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2017, I electronically filed the foregoing Second Amended Complaint with the Clerk of the Court for the U.S. District Court, Southern District of Texas, using the electronic case-filing system of the Court. The electronic case-filing system sent a "Notice of Electronic Filing" (NEF) to the following counsel of record, who consented in writing to accept the NEF as service of this document by electronic means:

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